

### **REMARKS**

Claim 57 is pending in the instant application. Applicants have amended Claim 57 to recite a method of modulating an immune response to an antigen by implanting within a mammal a device comprising a porous matrix containing said antigen within a container having a means for limiting the passive diffusion of molecules out of the device while permitting the active movement of immune cells into or out of said device. These amendments are supported by the specification at page 19, line 12 to page 20, line 4. Applicants have added dependent claims 58-76 which are directed to various embodiments of the invention.

### **THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN**

The rejection of claim 57 under 35 U.S.C. § 112, first paragraph for lack of enablement is overcome by the amendment to claim 57 above, for the reasons discussed below.

Claim 57 stands rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Specifically, the Office Action indicates that the specification of the current application is only enabling for a porous matrix contained within a perforated but otherwise impermeable container, and therefore would not enable one of ordinary skill in the art to practice a method commensurate in scope with claim 57. In particular, the Office Action relies on the specification, page 5, lines 13-17, for a recitation of what it identifies as the broadest interpretation of the device.

However, the specification clearly discloses and supports variations in the claimed device that allows it to operate following the principle of providing an artificial environment that mimics the composition and role of a lymph node. *See* page 12, lines 1-6. It accomplishes this by providing for a device that contains antigen and generates a diffusion barrier limiting the passive diffusion of antigen, cytokines, or immune factors from the device but permitting the active ingress and egress of immune cells from the device. *See* page 19, lines 12-18. The present application discloses an embodiment of the device wherein a porous matrix acts as a reservoir for the antigen and other molecules and a perforated but otherwise impermeable container is used to generate the diffusion barrier. In the context of the preferred embodiment, the specification acknowledges that one of ordinary skill in the art would recognize other means of readily accomplishing the principle of the novel device. *See e.g.*, Page 19, line 12-Page 23, line 7. Examples of such other means are described below.

First, with regard to the component of the container having a means for limiting the passive diffusion of molecules out of said device without limiting the active movement of immune cells into or out of said device, the instant specification at page 19, line 22, and at page 23, lines 4-5, discusses that a device comprising tubing may have its ends left opened, the open ends acting as perforations. Or with perforations, the tubing may be sealed. Furthermore, US patent application serial no. 10/017,457 (filed December 7, 2001), and published on June 26, 2003, as Publication US2003-0118630-A1, shows other means by which these features of the container may be readily achieved, such as drilling or the use of leachable solids in the wall polymer to generate holes (*See* paragraph [0033]). A copy of the published application is enclosed for the convenience of the Examiner.

Second, with regard to the porous matrix, further demonstration of alternate means to provide bioavailable antigen within the device is also described in Publication US2003-0118630-A1 mentioned above, i.e., the use of a fibrous scaffolding to achieve the same role as the polymeric matrix of the instant application (*See* paragraph [0009] and [0021] *et seqq.*).

Applicants submit that the instant specification is enabled with regard to teaching a person skilled in the art means for achieving the principle of the claimed method. In light of the foregoing, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Applicants have added dependent claims 58-76 to claim 57 that were among the original set of pending claims or disclosed in the specification. Correspondence of the new claims to those in the application as filed or as supported in the specification is set forth below:

New Dependent Claim	Support
Claim 58	Claim 2
Claim 59	Claim 3
Claim 60	Claim 4
Claim 61	Claim 5
Claim 62	Claim 6
Claim 63	Claim 7
Claim 64	Claim 8
Claim 65	Claim 9

Claim 66	P. 18, ll. 19-21
Claim 67	P. 12, ll. 6-8
Claim 68	Claim 10
Claim 69	Claim 10
Claim 70	Claim 30
Claim 71	Claim 46; p. 19, l. 22; p. 23, ll. 4-5
Claim 72	Claim 17
Claim 73	Claim 18
Claim 74	Claim 12
Claim 75	Claim 50
Claim 76	Claim 48

### CONCLUSIONS

Applicants respectfully request that the foregoing amendments and remarks be made of record in the file history of the instant application. Applicants submit that the remarks and amendments made herein now place the pending claims in condition for allowance. If a telephone discussion will help expedite processing of this application, the Examiner is invited to telephone the undersigned at (914) 762-7586.

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Respectfully submitted,

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